

with cutting/scoring elements attached, which is used in those circumstances where a high pressure balloon resistant lesion is encountered. A cutting/scoring PTCA catheter is intended for the treatment of hemodynamically significant coronary artery stenosis for the purpose of improving myocardial perfusion. A cutting/scoring PTCA catheter may also be indicated for use in complex type C lesions or for the treatment of in-stent restenosis.

(2) *Classification*. Class III (premarket approval). As of May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed. See § 870.3.

[75 FR 54496, Sept. 8, 2010]

§ 870.5150 Embolectomy catheter.

(a) *Identification*. An embolectomy catheter is a balloon-tipped catheter that is used to remove thromboemboli, i.e., blood clots which have migrated in blood vessels from one site in the vascular tree to another.

(b) *Classification*. Class II (performance standards).

§ 870.5175 Septostomy catheter.

(a) *Identification*. A septostomy catheter is a special balloon catheter that is used to create or enlarge the atrial septal defect found in the heart of certain infants.

(b) *Classification*. Class II (performance standards).

§ 870.5200 External cardiac compressor.

(a) *Identification*. An external cardiac compressor is an external device that is electrically, pneumatically, or manually powered and is used to compress the chest periodically in the region of the heart to provide blood flow during cardiac arrest.

(b) *Classification*. Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required*. No effective date has been established of the requirement for premarket approval. See § 870.3.

[45 FR 7907, Feb. 5, 1980, as amended at 52 FR 17737, May 11, 1987]

§ 870.5225 External counter-pulsating device.

(a) *Identification*. An external counter-pulsating device is a noninvasive device used to assist the heart by applying positive or negative pressure to one or more of the body's limbs in synchrony with the heart cycle.

(b) *Classification*. Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required*. No effective date has been established of the requirement for premarket approval. See § 870.3.

[45 FR 7907, Feb. 5, 1980, as amended at 52 FR 17737, May 11, 1987]

§ 870.5300 DC-defibrillator (including paddles).

(a) *Low-energy DC-defibrillator*—(1) *Identification*. A low-energy DC-defibrillator is a device that delivers into a 50 ohm test load an electrical shock of a maximum of 360 joules of energy used for defibrillating (restoring normal heart rhythm) the atria or ventricles of the heart or to terminate other cardiac arrhythmias. This generic type of device includes low energy defibrillators with a maximum electrical output of less than 360 joules of energy that are used in pediatric defibrillation or in cardiac surgery. The device may either synchronize the shock with the proper phase of the electrocardiogram or may operate asynchronously. The device delivers the electrical shock through paddles placed either directly across the heart or on the surface of the body.

(2) *Classification*. Class II (performance standards).

(b) *High-energy DC-defibrillator*—(1) *Identification*. A high-energy DC-defibrillator is a device that delivers into a 50 ohm test load an electrical shock of greater than 360 joules of energy used for defibrillating the atria or ventricles of the heart or to terminate other cardiac arrhythmias. The device may either synchronize the shock with the proper phase of the electrocardiogram or may operate asynchronously. The device delivers the electrical shock through paddles placed either directly across the heart or on the surface of the body.